The opinion in support of the decision being entered is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

JUN 28 2001

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID V. GOEDDEL and MIKE ROTHE

Appeal No. 1999-1372
Application No. 08/779,599

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 31-33, which are all the claims pending in the application.

Claim 31 is illustrative of the subject matter on appeal and is reproduced below:

31. An isolated human tumor necrosis factor receptor associated factor (TRAF) prepared by

(a) screening a human recombinant cDNA library prepared from tissue expressing human TNF- R2 at a detectable level with one or more labeled oligonucleotide probe(s) having about 30 to 50 bases derived from the nucleotide sequence encoding murine TRAF1 (SEQ.ID. NO:1) or murine TRAF2) (SEQ.ID. NO:3), wherein said probe(s) are designed based on TRAF1 or TRAF2 regions which have the least codon redundance, under stringent conditions comprising overnight incubation at 42 C in a solution comprising 20% formamide, 5xSSX, 50mM sodium phosphate (pH 7.6), 5x Denhardt's solution, 10% dextran sulfate, and 20 g/ml denature, sheared salmon spern DNA;

(b) inserting the DNA hybridizing to said probe(s) into a replicable expression vector;

(c) transforming a recombinant host cell with said expression vector;

(d) culturing the transformed host cell; and

(e) recovering said human TRAF.

In contrast to the examiner's statement (Answer[1], page 2), the reference relied upon by the examiner is:

Lewis et al. (Lewis), "Cloning and expression of cDNAs for two distinct murine tumor necrosis factor receptors demonstrate one receptor is species specific," Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 2830-2834 (1991).

GROUNDS OF REJECTION

Claims 31-33 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure that fails to adequately describe the claimed

[1] Paper No. 17, mailed July 30, 1998.

invention, in addition to failing enable one skilled in the art to make and use the claimed invention.

Claims 31-33 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite in the use of the acronym "TRAF", and in the use of the term "about".

We reverse.

DISCUSSION

In reaching our decision in this appeal, we considered appellants' specification and claims, in addition to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer for the examiner's reasoning in support of the rejections. We further reference appellants' Brief[2] for the appellants' arguments in favor of patentability.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 3)

> Claims 31 to 33 are rejected under 35 U.S.C. [§] 112, first paragraph, as containing subject matter which is not described in the instant specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claim[ed] invention or to enable one skilled in the art to make and use the claimed invention....

Appellants argue (Brief, page 6) that the "written description and enablement requirements of 35 U.S.C. 112, first paragraph were not separately analyzed" [emphasis removed] by the examiner. Appellants then explain (Brief,

[2] Paper No. 16, received May 18, 1998.

pages 6-8) that "[t]he written description and enablement requirements of § 112, first paragraph are separate and distinct from each other."

As stated in Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (CAFC 1991):

> With respect to the first paragraph of §112 the severability of its "written description" provision from its enablement ("make and use") provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967). Although the appellants in that case had presumed that the rejection appealed from was based on the enablement requirement of §112, id. at 995, 154 USPQ at 123, the court disagreed:
>
> > [t]he question is not whether [one skilled in the art] would be so enabled but whether the specification disclosed the compound to him, specifically, as something appellants actually invented. ... If [the rejection is] based on section 112, it is on the requirement thereof that "The specification shall contain a written description of the invention ...."

Id. at 995-996, 154 USPQ at 123. The issue, as the court saw it, was one of fact: "Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound [claimed]?" Id. at 996, 154 USPQ at 123. [emphasis and modification original]. Accordingly we will review the written description and enablement issues of the examiner's rejection separately.

Written Description:

On this record, the examiner relies on Amgen Inc. v. Chugai Parmaceuticals Co. Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), and

UC v. Eli Lilly and Co., 119 F. 3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) to support his conclusion (Answer, page 9) that:

> Because the instant specification does not identify those properties which distinguish a human tumor necrosis factor receptor associated factor from a tumor necrosis factor receptor associated factor of baboon, rat, cow or, particularly, murine origin one would conclude that [a]ppellant[s] was [sic] not in possession of the claimed invention at the time the instant application was filed.

In response, appellants' argue (Brief, page 15) with reference to Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)[3] that in contrast to a product claim, e.g. a purified and isolated DNA sequence (see Amgen 927 F. 2d at 1204, 18 USPQ2d at 1019), "conception of a process for making a substance can constitute a conception of the substance itself claimed as a process, i.e. in a product-by-process format." Compare, Fiers, 984 F.2d at 1169, 25 USPQ2d at 1605.

Notwithstanding appellants' argument to the contrary, the examiner maintains (citing Fiers, 984 F.2d at 1170, 25 USPQ2d at 1606) that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." According to the examiner (Answer, page 10):

> The instant claims are drawn to an isolated protein which is claimed only as a product-by-process. There is no adequate written description of that protein "such as by structure, formula, chemical name, or physical properties". The recited process through which

[3] We note that appellant incorrectly refers (Brief, page 14) to this decision as Fiers v. Sugano, 25 USPQ 1505 (1993).

> the protein is to be made expressly requires an isolated cDNA encoding a human TRAF. The instant specification does not describe a cDNA encoding a human TRAF "by structure, formula, chemical name, or physical properties". The steps recited in the product-by-process claims constitute nothing more than a potential method of isolating that cDNA. Therefore the instant specification fails at several levels to provide an adequate written description of an isolated human TRAF, as claimed.

While the examiner's rationale blurs the distinction between written description and enablement, we, for the moment, will continue our focus on the written description issue. The examiner recognizes that appellants' product-by-process claims are drawn to a protein, TRAF, which is claimed in terms of the process for making the protein. Nevertheless, the examiner finds that "[t]here is no adequate written description of that protein 'such as by structure, formula, chemical name, or physical properties'." Notwithstanding, appellants' emphasis on the distinction between product and product-by-process claims, the examiner misses the subtlety of the principles set forth in Amgen, Lilly, and Fiers. The claims of Amgen[4], Lilly[5], and Fiers[6] are drawn to products.

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[4] 927 F.2d at 1204, 18 USPQ2d at 1019 claim "2. [a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."

[5] According to appellants (Brief, page 13) "the claim considered by the CAFC read as follows: '[a] DNA transfer vector comprising a deoxynucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxynucleotide sequence coding for human proinsulin.'"

[6] 984 F.2d at 1171, 25 USPQ2d at 1605 "[t]he present count is to a product, a DNA which codes for b-IF; it is claim to a product having a particular biological activity or function, and in Amgen, we held that such a product is not conceived until one can define it other than by its biological activity or function.

As set forth in Lilly, 119 F. 3d at 1559, 43 USPQ2d at 1404 "[a]n adequate written description of a [product] DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)." This, however, is in regard to a product claim, not a product-by-process claim. The Fiers court made clear that:

> Our statement in Amgen that conception may occur, inter alia, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognized that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. [With] [a] product-by-process claim ... conception only of a process for making a substance ... can ... constitute a conception of the substance claimed as a process. [However] [c]onception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

Nothing in Lilly conflicts with the principles set forth in Amgen and reaffirmed in Fiers. Appellants' claims on this record are product-by-process claims. On this record, the examiner has not considered the written description issue with regard to appellants' product-by-process claims.

In addition, we disagree with the examiner's conclusion (Answer, page 10) that "[t]he steps recited in the product-by-process claims constitute nothing more than a potential method of isolating that cDNA." With regard to claim 31, step "(a)" is directed to obtaining a cDNA. Steps "(b)" through "(e)" are directed to expressing and recovering the TRAF protein encoded by the cDNA obtained in

step "(b)". Therefore, in contrast to the examiner's position, appellants' product-by-process claims constitute much "more than a potential method of isolating that cDNA."

Enablement:

With regard to whether appellants' disclosure enables one of ordinary skill in the art to make and use the claimed invention, we note that "[w]hen rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

In In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988), our appellant reviewing court set forth factors to be considered in determining whether a disclosure would require undue experimentation:

> They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims [footnote omitted].

We recognized, as set forth in Enzo Biochem., Inc. v. Calgene, Inc., 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999) that "the Wands factors 'are illustrative, not mandatory ... [and] [w]hat is relevant depends on the facts'" [citation omitted]. However, this does not mean that the factors can be ignored.

Accordingly, we do not agree with the examiner's statement (Answer, page 6) that "the instant claims have not been rejected for undue breadth and, therefore, the factors considered in Wands is not at issue." The examiner's statement of the rejection is directed, inter alia, to the specification's enabling description of how to make and use the claimed invention. The Wands factors are not limited only to scope of enablement issues, instead the factors are applicable any time the enabling description of a specification is in question. Therefore, the examiner's statement that "the factors considered in Wands is [sic] not at issue" constitutes reversible error.

We note appellants' application of the Wands factors to their claimed invention (Brief, pages 16-21), and conclusion (Brief, page 21) that "one

reasonably skilled in the art could have practiced the invention claimed ... without undue experimentation." However, we see no rebuttal, by the examiner, of appellants' findings through their application of the Wands factors.

In our opinion, for the reasons set forth above, the examiner has not presented the evidence necessary to maintain the written description and enablement rejections of claims 31-33. Accordingly, we reverse the rejection of claims 31-33 under 35 U.S.C. § 112, first paragraph as being based on a disclosure that fails to provide a written description of the claimed invention, in addition to failing enable one skilled in the art to make and use the claimed invention.

In addition, we note with interest, claim 5 of United States Patent No. 5,869,612 ('612 patent)[7]. Claim 5 of the '612 patent reads as follows:

> 5. An isolated native mammalian tumor necrosis factor receptor associated factor (TRAF) encoded by nucleic acid capable of hybridizing, under stringent conditions, to the complement of the nucleic acid of SEQ. ID. NO:1 or SEQ. ID. NO:3.

It appears from a review of the '612 patent that the patented mammalian TRAF factor and the human TRAF factor of this appeal are closely related and the scope of the claims overlap each other. Thus it appears that the continued rejection of the claims in the present application under 35 U.S.C. 112, first paragraph, is inconsistent with the determination that claim 5 is patentable. While the examiner may issue a rejection if appropriate under these

[7] '612 and the instant application of appeal are both continuations of the same parent, United States Patent No. 5,708,142.

circumstances, such a rejection would appear to require the signature of the Group Director. Compare Manual of Patent Examining Procedure (MPEP) § 2307.02 (7th ed., July 1998). We note the Group Director did not sign the examiner's action.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

As set forth in Amgen, 927 F.2d at 1217, 18 USPQ2d at 1030:

> The statute requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits.").

Furthermore, claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

According to the examiner (Answer, page 5) "[i]t is unclear what additional functional and/or structurally [sic] limitations are placed upon the claimed isolated human protein by the presence of the term 'TRAF' in these claims." The examiner argues (id.) that "[t]he text in the last paragraph on page 5 of the

instant specification provides a basis for the origin of this term but it does not provide an unambiguous definition of it."

In contrast to the examiner's position one needs to look no further than claim 31 for an "unambiguous definition" of the term "TRAF." According to claim 31, "TRAF" is an acronym for "tumor necrosis factor receptor associated factor." In addition, it is unclear, why the examiner finds that this acronym must place some functional or structural limitation on the claimed invention. We are aware of no legal precedent, and the examiner provides none, that would require appellants' use of an acronym to place a functional or structural limitation on the claimed invention.

The examiner also finds (Answer, page 5) claims 31-33 "are indefinite because the term 'about 30 to 50 bases' is vague and indefinite since one can not distinguish between that which is encompassed by this term and that which is excluded." The examiner argues (Answer, bridging paragraph, pages 5-6) that "[w]hereas one could reasonably interpret the term 'about a gallon' as including any volume which is more than three fourths of a gallon to less than a gallon and one fourth, one can not interpret 'about 30 nucleotide bases' as more than 29.5 bases and less than 30.5 bases." However, as set forth in Modine Manufacturing Co. v. U.S. International Trade Commission, 75 F. 3d 1545, 1557, 37 USPQ2d 1609, 1617 (Fed. Cir. 1996):

> Mathematical precision should not be imposed for its own sake; a patentee has the right to claim the invention in terms that would be understood by persons of skill in the field of the invention. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613,

> 624, 225 USPQ 634, 641 (Fed. Cir.), cert. dismissed, 474 U.S. 976 (1985)("if the language is as precise as the subject matter permits, the courts can demand no more").

In our opinion, a person of skill in this field would understand that "nucleotide bases" can not be represented by fractional units.

The examiner further argues that "the use of the term 'about' to delineate the number of nucleotide bases in a polynucleotide is inappropriate since there appears to be nothing to prevent [a]ppellant [sic] from simply reciting a greater or lesser number of polynucleotide bases if this is what they regard as the invention." We recognize that the issue here is somewhat similar to Amgen 927 F. 2d at 1216, 18 USPQ2d at 1031 wherein the court affirmed a district court ruling of indefiniteness of the term "at least about 160,000" international units per absorption unit (IU/AU). In Amgen the "at least about 160,000" language was added after the examiner rejected "at least 120,000" which the examiner found was anticipated by the prior art. Id. at 1218. The district court held the claims invalid because it found that the term "about" failed to advise one skilled in the art of the "mean value" between the prior art value of 128,620 IU/AU and the "mean specific activity level of 160,000" that would constitute infringement. Id. 927 F. 2d at 1218, 18 USPQ2d at 1030. The district court reasoned that use of the term "about" coupled with the form of measurement used, which the court found to be imprecise, failed to distinguish the invention over "the close prior art." Id. 927 F. 2d at 1217, 18 USPQ2d at 1031.

However, unlike the present situation, because Amgen had close prior art, the court required more precision when considering the scope of the term "about." Amgen 927 F. 2d at 1218, 18 USPQ2d at 1031 ("when the meaning of the claims is in doubt, especially when, as is the case here, there is close prior art, they are properly declared invalid"). The Amgen court cautioned against a per se application of their holding as it applies to the term "about". Id. 927 F.2d at 1218, 18 USPQ2d at 1031 ("we caution that our holding that the term 'about' renders indefinite ... should not be understood as ruling out any and all use of this term in patent claims"). Instead the court explains, citing W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983) that the term about "may be acceptable in appropriate fact situations."

As set forth in Georgia-Pacific Corp. v. United States Plywood Corp., 258 F.2d 124, 136, 118 USPQ 122, 132 (2d Cir.), cert. denied, 358 U.S. 884, 119 USPQ 501 (1958), "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." On this record appellants' specification (page 36) discloses that:

> Once cDNA encoding a TRAF from one species has been isolated, cDNAs from other species can also be obtained by cross-species hybridization. According to this approach, human or other mammalian cDNA or genomic libraries are probed by labeled oligonucleotide sequences selected from known TRAF sequences (such as murine TRAF-1 and TRAF-2 as disclosed in the present application) in accord with known criteria, among which is that the sequence should be sufficient in length and sufficiently

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Ginger R Dreger
Genentech Inc
460 Point San Brun Boulevard
South San Francisco CA 94080-4990

> unambiguous that false positives are minimized. Typically, a ^{32}P-labeled oligonucleotide having about 30 to 50 bases is sufficient, particularly if the oligonucleotide contains one or more codons for methionine or trypophan.

Therefore it appears to us that when appellants' claims are read in light of the specification, a person of ordinary skill in the art would understand that the phrase "oligonucleotide probe(s) having about 30 to 50 bases" refers to oligonucleotide probes having a length and sequence necessary to minimize the number of false positives obtained. In addition, unlike the facts in Amgen, on this record, the examiner has applied no prior art to which appellants amended their claimed invention around. Therefore, the facts in this case are distinguishable from the facts in Amgen.

We note that the examiner failed to address appellants' response (Brief, pages 22-23) regarding both of the examiner's rejections under 35 U.S.C. § 112, second paragraph. Accordingly, for the reasons set forth above, we reverse the examiner's rejections under 35 U.S.C. § 112, second paragraph

REVERSED

Sherman D. Winters)
Administrative Patent Judge)
)
William F. Smith) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Donald E. Adams) INTERFERENCES
Administrative Patent Judge)